Restless Legs Syndrome Prevalence and Impact

REST General Population Study

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Background: Restless legs syndrome (RLS), a common sensorimotor disorder, has a wide range of severity from merely annoying to affecting sleep and quality of life severely enough to warrant medical treatment. Previous epidemiological studies, however, have failed to determine the prevalence of those with clinically significant RLS symptoms and to examine the life effects and medical experiences of this group.

Methods: A total of 16 202 adults (aged ≥18 years) were interviewed using validated diagnostic questions to determine the presence, frequency, and severity of RLS symptoms; respondents reporting RLS symptoms were asked about medical diagnoses and the impact of the disorder and completed the Short Form-36 Health Survey (SF-36). Criteria determined by RLS experts for medically significant RLS (frequency at least twice a week, distress at least moderate) defined “RLS sufferers” as a group most likely to warrant medical treatment.

Results: In all, 15 391 fully completed questionnaires were obtained; in the past year, RLS symptoms of any frequency were reported by 1114 (7.2%). Symptoms occurred at least weekly for 773 respondents (5.0%); they occurred at least 2 times per week and were reported as moderately or severely distressing by 416 (2.7%). Of those 416 (termed RLS sufferers), 337 (81.0%) reported discussing their symptoms with a primary care physician, and only 21 (6.2%) were given a diagnosis of RLS. The SF-36 scores for RLS sufferers were significantly below population norms, matching those of patients with other chronic medical conditions.

Conclusion: Clinically significant RLS is common (prevalence, 2.7%), is underdiagnosed, and significantly affects sleep and quality of life.

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RESTLESS LEGS SYNDROME (RLS) is a neurological sensorimotor disorder characterized by the following 4 diagnostic criteria: an urge to move that is usually associated with abnormal sensations in the legs, and symptoms that are engendered or worsened by rest, relieved by movement, and most severe at night. Although the condition was probably first described in the 17th century, the pioneering clinical studies were carried out in the 1940s by Ekbom, who recognized the adverse effects of RLS on sleep and daytime functioning. (Restless legs syndrome is sometimes referred to as Ekbom syndrome.) More recently, research has shown that RLS negatively affects sleep, cognitive function, and quality of life.

Population-based studies using the full standard diagnostic criteria for RLS report a prevalence of 5% to 10% in western industrial countries, but a lower prevalence in Asian populations.

Restless legs syndrome has a wide range of severity, from minimally annoying and somewhat infrequent to severely disruptive of life. The aims of the RLS Epidemiology, Symptoms, and Treatment (REST) program were to characterize the epidemiology of RLS in a general population, both for any significant degree and for a clinically significant degree of the disorder that, in the opinion of RLS experts, is frequent and distressing enough to warrant consideration for treatment. We present herein the first data from a large, multinational general population in which current diagnostic criteria for RLS were used. To our knowledge, this is the first report to characterize those with what experts judge to be a clinically significant degree of the disorder. Our results characterize patients whose RLS symptoms probably require medical attention and provide some indication of the current response by physicians (in terms of diagnosis and treatment) to their patients’ report of symptoms. A companion study, the REST primary care study, has assessed the fre-
frequency, symptoms, and treatment of RLS in a multinational primary care population.

**METHODS**

The REST general population study was conducted in the United States and 5 European countries (France, Germany, Italy, Spain, and the United Kingdom). In the United States, quotas matching the overall population were placed on the 4 US Census regions (Northeast, Midwest, South, and West) and sorted by male and female, generating 8 quota groups (half male and half female in each region). Trained telephone interviewers then carried out the population survey for the US sample; each telephone number was selected by means of random-digit dialing. The sample called provided the same proportion of numbers for each state and matched the distribution of the national population.

In Europe, face-to-face interviews were undertaken by experienced interviewers using a computer-assisted personal interviewing omnibus. Interviews of persons 18 years or older were undertaken in a number of randomly selected locations to achieve a national spread within each of the 5 European countries. Respondents were then randomly selected from postal address files, telephone directories, or voting registers, but with quotas set for age, sex, and working/social status to ensure that the sample was nationally representative.

Respondents were asked to complete a questionnaire consisting of 3 parts (Table 1). Part 1 collected background information on recent medical consultations and current diagnoses. Part 2 comprised the 4 diagnostic questions for RLS, which were based on standard diagnostic criteria, and collected information about the frequency of RLS symptoms and the degree of associated distress. Part 3 was administered only to those who responded positively to part 2 and was designed to collect more detailed information on the frequency, nature, and impact of RLS symptoms, consultation rates, diagnosis, and treatment.

Responses were analyzed to produce an estimate of the prevalence of RLS symptoms of any frequency and of specific frequencies. A subpopulation of “RLS sufferers” was defined whose symptoms occurred at least twice weekly during the past 12 months and were reported to be moderately or extremely distressing. This definition was chosen to focus on those judged by a panel of 5 RLS experts as having clinically significant symptoms that were likely to warrant treatment.

The analysis focused primarily on descriptive statistics and χ² statistics to identify significant relationships (a significant result being P<.05).

Answers to the Short Form-36 Health Survey (SF-36) were obtained from the subpopulation of RLS sufferers by the same methods used for obtaining the answers to the other survey questions (face-to-face vs telephone reading of the questions with verbal replies). The SF-36 was developed for the Medical Outcomes Study and has been extensively tested and validated. The questionnaire assesses the following 8 dimensions of health-related quality of life: physical functioning, physical limitations on normal role activities, bodily pain, general health, energy and vitality, social functioning, emotional limitations on normal role activities, and mental health. The SF-36 data were analyzed separately for each country. The number of RLS sufferers who completed the SF-36 was inadequate for comparison with their country norms except for the sample from the United States (n=158). The mean SF-36 scores of US RLS sufferers were compared statistically with age- and sex-adjusted US population norms using the t test, with the level for statistical significance set at P<.05. Scores for US patients with RLS symptoms were also compared with scores obtained from patients with other chronic medical conditions.

**RESULTS**

**SURVEY POPULATION**

A total of 16 202 people were approached to be interviewed (10 188 in Europe and 6014 in the United States); 98.2% agreed to the interview and 15 391 (95.0%) fully completed questionnaires were obtained from respondents who were 18 years or older. Sample sizes by country are presented in Table 2. The survey population as a whole did not differ markedly from international and country norms (derived from the Mattson Jack Epidemiology Database [http://www.mattsonjack.com/]) for sex distribution (χ²=3.36, P>.05). For age distribution, the survey population was closely matched to international norms for most age groups (Figure 1 A), but individuals 80 years and older were underrepresented and those aged 20 to 29 years were slightly overrepresented compared with the norms. This resulted in a statistically significant difference between the 2 populations (χ²=116.18, P<.001). The flow of respondents through the survey is summarized in Figure 2.

**EPIDEMIOLOGY**

Of the 15 391 respondents, 1114 (7.2%) reported all 4 diagnostic symptoms of RLS at any frequency and 773 (5.0%) experienced symptoms at least weekly. Four hun-
dred sixteen respondents (2.7%) met the criteria for RLS sufferers, ie, they reported that moderately or severely distressing symptoms consistent with RLS occurred at least twice weekly. The proportion of RLS sufferers in the survey population ranged from 1.3% in Germany to 4.2% in France (Table 2). The overall differences between countries for the prevalence of RLS was not statistically significant (F=0.72, P = .40)

The prevalence of RLS was generally approximately twice as high for women as it was for men (9.0% vs 5.4% for any frequency of symptoms, 6.2% vs 2.8% for symptoms ≥1/wk, and 3.7% vs 1.7% for women vs men in the subpopulation of RLS sufferers). The prevalence of RLS sufferers was higher for women in all age groups (Figure 1B). Women experiencing RLS symptoms at any frequency were asked about pregnancy status; 12 reported being pregnant and 6 (50%) of these met the criteria for RLS sufferers. This was somewhat larger than the 40.1% of all women with RLS who were classified as being RLS sufferers. For men with any RLS symptoms, 31.7% met the criteria for an RLS sufferer.

The prevalence of RLS sufferers increased with age up to age 79 years and then declined (Figure 1B). A comparison of the age profile of the groups with and without RLS symptoms showed that RLS sufferers were older (Figure 1C). However, 150 (36.1%) of the 416 RLS sufferers were 49 years or younger.

**SYMPTOMS**

In response to more detailed questioning, RLS sufferers reported the symptoms they experienced most often, choosing from a list of 14 symptoms in 5 categories (Table 3). The percentage of RLS sufferers reporting symptoms for each category was 88.0% for sensory symptoms, 75.5% for sleep-related symptoms, 55.5% for disturbance of daytime functioning, 37.0% for symptoms affecting movement, and 26.2% for mood disturbance; 59.4% reported pain associated with their RLS symptoms. When asked which symptom was most troublesome, 45.7% of the RLS sufferers mentioned one of the sensory symptoms (including 19.0% who mentioned pain), 37.8% mentioned a sleep-related symptom, and 6.9% mentioned symptoms disturbing daytime functioning.

**IMPACT ON DAYTIME FUNCTIONING AND QUALITY OF LIFE**

**Questionnaire Responses to Impact of Symptoms**

The RLS sufferers were asked which, if any, of 9 aspects of daytime functioning were affected when they had symptoms (Table 4). Most (85%) reported that their RLS symptoms disturbed 1 or more of these specific daytime symptoms. The items most commonly reported to be affected were negative influence on mood (30.5%), lack of energy (47.6%), and disturbance of normal daily activities (40.1%).

**SF-36 Survey Responses**

Responses to the SF-36 were obtained from 384 RLS sufferers, of whom 375 answered every domain. In general, RLS sufferers had lower quality-of-life scores than the general population, as measured by the SF-36. A comparison between the mean SF-36 scores of RLS sufferers and age- and sex-adjusted US population norms is presented in Figure 3. An examination of results from the European countries compared the results from each country with the population norms for that country and showed that the values were lower than population norms in all domains, but the sample sizes were too small to permit statistical analyses.

A comparison of RLS data with results for other chronic medical conditions in US populations13 indicated that RLS sufferers had SF-36 scores similar to those of patients with other medical conditions, such as type 2 diabetes mellitus, depression, and osteoarthritis with hypertension (Figure 4).

**CONSULTATION RATES**

A large proportion (n=416) of RLS sufferers had discussed their symptoms with a primary care physician (PCP); 61.3% reported doing so in the past 12 months and 81.0% had done so at any time. In the past 3 months,
75.5% of the RLS sufferers had consulted a PCP for any reason and 46.6% had consulted a specialist, compared with 54.3% and 33.7%, respectively, for an age- and sex-matched set drawn from the survey population who were not considered RLS patients \( (P < .001, \chi^2 \text{ test}) \). Specialists consulted (in the order of frequency) included neurologists, cardiologists, rheumatologists, phlebologists or vascular surgeons, psychiatrists, diabetologists or endocrinologists, sleep specialists, and geriatricians.

**DIAGNOSIS RATES**

Of the 416 RLS sufferers, 337 (81.0%) reported discussing their symptoms with a physician (Figure 2). Of these, 252 (74.8%) recalled receiving a diagnosis for their symptoms. The most common diagnosis was “poor circulation” (18.3% of those receiving a diagnosis), followed by arthritis (14.3%), and back/spinal injury or problem (12.7%). Varicose veins (7.5%), depression/anxiety (6.3%), and trapped nerve (5.6%) were also commonly diagnosed in RLS sufferers. Only 21 sufferers (6.2%) indicated that they were given a diagnosis of RLS.

**COMMENT**

To our knowledge, REST is the first large-scale, multinational, population-based profile study of RLS that uses the full standard diagnostic criteria, and it is the only large study of RLS that has systematically investigated quality of life. This study, like the associated primary care study, is structured to identify those individuals considered likely to warrant treatment (RLS sufferers). The results clearly demonstrate the significant negative impact of RLS on sleep, subsequent daytime performance, and quality of life for these RLS sufferers.

**PREVALENCE**

Our survey population covers a wide geographic area. A rigorous sampling method was designed to ensure that the sample being interviewed provided a demographic balance—for age, gender, working/social status, and region—to achieve nationally representative samples. The results, therefore, give a picture of RLS that can be generalized to more than 400 million people in western industrial countries.

It is true that we have classified patients as suffering from characteristic symptoms of RLS on the basis of their self-report. However, the diagnostic questions in our sur-
vey were based on the current diagnostic standards and have been validated in a study in primary care, showing a diagnostic sensitivity of 82.3% and a specificity of 89.9%.

Previous smaller studies indicated an RLS prevalence of 5% to 10% in the general population that increases with age until at least the eighth decade of life and is higher in women than in men. We had a comparable prevalence estimate of 7.2% for RLS symptoms of any frequency. In our study, the RLS sufferers, who reported symptoms at least twice weekly combined with moderate or severe distress, also showed the same pattern of prevalence being greater in women and increasing with age. Pregnancy among women with RLS symptoms was uncommon, occurring in only 12 subjects and thus having no significant impact on the analyses. Nonetheless, for subjects with RLS, the risk of being in the group of RLS sufferers was increased by being pregnant and decreased by being male.

Although the prevalence of RLS sufferers increases with age (Figure 1B), we found RLS sufferers among people of all ages. Indeed, 36.1% of the RLS sufferers were 49 years or younger (Figure 1C). Thus, RLS should not be classified as a condition that exclusively or primarily affects the elderly.

Despite the use of different survey techniques, we did not find any differences in prevalence between the United States and Europe. The refusal rate was low (1.8%) and had no measurable impact on our results. There is no indication that the differences in survey techniques significantly biased the results. The one significant difference for individual countries was the somewhat higher prevalence of RLS sufferers in France. This may have resulted by chance or it may represent a founder effect. A similar difference was reported in Canada, with a higher prevalence among persons of French vs English descent.

### IMPACT ON QUALITY OF LIFE

Our results identify the marked negative impact of RLS symptoms on sleep. More than 75% of the RLS sufferers reported at least 1 sleep-related symptom. Disrupted sleep, an inability to fall asleep, and insufficient hours of sleep are expected consequences of the sensorimotor abnormalities of RLS, which are worse at night and while at rest. Many RLS sufferers reported performance-related effects, presumably resulting from RLS-related sleep disruption, such as daytime sleepiness and difficulty in concentrating the following day. Sleep disruption has also been associated with negative effects on cognitive function in patients with RLS. Thus, RLS should be consid-
Considered within the differential diagnosis when a patient complains of sleep abnormalities, such as an inability to fall asleep and frequent wakefulness during the night.

Restless legs syndrome suffers had a reduced quality of life compared with adjusted population norms (as measured by the SF-36 for the US sample). The reduced quality of life for RLS sufferers appears comparable with that experienced by those with other serious chronic medical conditions, such as type 2 diabetes mellitus and clinical depression. The results herein are also supported by another, smaller study of RLS in a clinical population that compared their data with population norms. These data from 2 different studies strongly support the need to ensure that RLS is recognized and treated appropriately.

**RLS SUFFERERS’ EXPERIENCE WITH MEDICAL CONSULTATION**

The fact that 81% of our respondents categorized as RLS sufferers had discussed their symptoms with a physician indicates that patients with this degree of RLS symptoms are likely to seek medical attention. Moreover, those with RLS symptoms had significantly higher consultation rates with both

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**Figure 3.** Comparison of mean Short Form 36 Health Survey (SF-36) scores of patients with restless legs syndrome (“RLS sufferers”) with age- and sex-adjusted US population norms. Asterisks indicate that the scores of the RLS sufferer group were significantly below the norms for all 8 dimensions.

**Figure 4.** Comparison of mean Short Form 36 Health Survey (SF-36) scores of US patients with restless legs syndrome (“RLS sufferers”) with those of US patients with common chronic medical conditions.
PCPs and specialists compared with a matched set drawn from the remainder of the sample. Thus, the RLS sufferers characterized by the REST study correspond to those RLS patients most likely to be encountered in clinical practice.

However, despite seeking medical help, only 6.2% reported having received a diagnosis of RLS. The low rate of diagnosis given to those presenting with RLS symptoms reflects the current lack of understanding of the disorder. Because RLS is not generally recognized as a medically significant disorder, there may be a tendency to account for these RLS symptoms as an expression of better recognized medical conditions, such as pain syndromes associated with a back injury, peripheral neuropathy, or arthritis. The failure to diagnose and treat RLS leaves the patient with unnecessary suffering for 2 reasons. First, the patient fails to receive effective treatments such as dopamine agonists. Second, focusing medical attention on the other conditions mistakenly identified with the RLS may lead to unnecessary treatments that incur extra cost and adverse effects. The clinician needs to know that RLS is not generally caused by the common pain syndromes (eg, peripheral neuropathy, diabetes, and osteoarthritis). Education about RLS should emphasize both the defining features and the differential diagnosis with other conditions that produce leg problems. A companion study has indeed shown that this failure to diagnose RLS extends to a failure to prescribe appropriate medications.

**IMPLICATIONS FOR MEDICAL CARE**

The presence or absence of the key diagnostic criteria for RLS can be easily determined by asking 4 diagnostic questions. Thus, if clinicians, particularly PCPs, were aware of the profile and impact of RLS, diagnosis rates would likely improve and inappropriate treatments would be reduced. In addition, if current guidelines for diagnosis and treatment were more widely disseminated to PCPs, misdiagnoses and unnecessary referrals could be reduced.

In conclusion, the results of the REST general population study provide an important initial step in the understanding of RLS as encountered in clinical practice. The symptoms of RLS, particularly sleep-related symptoms, are sufficiently distressing and debilitating such that many sufferers seek medical treatment. Hence, improved diagnosis of RLS should not result in an increase in physicians’ workloads. On the contrary, increased diagnosis resulting from increased understanding and awareness of the condition is essential for providing effective treatment.

These results deserve careful consideration by all clinicians responsible for the diagnosis and management of those with RLS.

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